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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/803,444

03/17/2004

Eric A. Goldfarb

020489-000410US

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09/15/2008

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EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

09/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/803,444	Applicant(s) GOLDFARB ET AL.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-15,17-19,21-30 and 32-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6-15,17-19,21-30 and 32-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/19/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 10, 2008 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 18, 19, 21-30, and 35-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe at least two distal and at least two proximal elements that adjust in length in each of the elements, where the length traverses from the distal end of the element to a distal end of the shaft, and where the length "correspond[s] to a length of the leaflets." On page 9, paragraph [0028] and page 25, paragraph [0100] of the specification, the

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elements are said to protrude "various distances from the shaft" or "various distances and at various angles from the shaft," but the elements are not said to have lengths corresponding to a length of a leaflet.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 6-15, 17, and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Bush et al. (5,282,845). Bush et al. disclose, at least in figures 13-15 and col. 5, lines 59-61 and col. 9, line 55 to col. 10, line 14; an interventional tool for repairing a cardiac valve, where the tool includes a catheter (14i) having a shaft, a proximal portion, a distal portion, a capture device (18i) detachably connected to the catheter (e.g., at assembly or disassembly of the capture device and the catheter) having at least two extendable distal elements (longer 18i), and at least two extendable proximal elements (shorter 18i), where each of the proximal and distal elements have a proximal end adjacent to the shaft and a distal end, where the distal elements and the proximal elements are independently deployable and self-expand (by spring action) in an outward radial direction from the shaft to a deployed position and to positions between a retracted position to the deployed position, where extending the at least two distal and at least two proximal elements adjusts a length in each of the elements, the length traversing from the distal end of the shaft to the distal end of the element; where

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the elements are adapted to atraumatically capture the valve leaflets (with curvilinear surfaces), where at least the two distal elements include a frictional accessory (80, which slidably engages the elements with friction between the elements and the accessory), where the at least two proximal elements and the at least two distal elements are adapted to be adjusted angularly after capturing the leaflets, where the distal portion comprises two distal elements on opposite sides of the shaft and are simultaneously deployable, where the proximal portion comprises two proximal elements on opposite sides of the shaft and are simultaneously deployable, where the at least two proximal elements and the at least two distal elements have a loop shape when deployed, where the at least two proximal elements and/or the at least two distal elements are comprised of a metal (e.g., platinum-iridium alloy), where at least two distal elements and at least two proximal elements are adapted to fixedly hold the leaflets as captured, and where the at least two proximal elements are configured to be disposed within the edges of the corresponding at least two distal elements when both the at least two proximal elements and the at least two distal elements are in a deployed position (i.e., the edges of the proximal elements are within the radius from the shaft as defined by the edges of the distal elements), where the at least two proximal elements are held in the retracted position under tension (i.e., by bending caused by spring force and by frictional engagement of the elements with the shaft lumen during movement of the elements within the shaft and before deployment of the elements), where deploying the at least two proximal elements comprises releasing the tension, and where tension

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is provided by a strand of material (80) or a suture (the wire that forms 80) coupled to the at least two distal elements.

Note: The introductory statement of intended use ("for repairing a cardiac valve") has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the device of Bush et al., which is capable of being used as claimed if one desires to do so.

Response to Amendment

6. The rejection under 35 U.S.C. 112, 1st paragraph, of claims 1, 6-15, 17, and 32-34 is hereby withdrawn. With respect to Applicant's arguments with respect to claims 1, 6-15, 17 and 32-34, Bush et al. indeed disclose a capture device detachably connected to the catheter. That is, the capture device is slidable relative to the catheter, and the capture device is removable from the catheter during assembly or disassembly of the tool.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773

September 12, 2008